IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

TALISA TAYLOR AND JEFF TAYLOR, Plaintiff, vs. C.R. BARD, INC., Defendant.	CIVIL ACTION FILE No.: _____ JURY TRIAL DEMANDED

COMPLAINT FOR PERSONAL INJURIES, PERMANENT INJURIES, PAIN AND SUFFERING, MEDICAL EXPENSES, LOST EARNINGS, DIMINISHED EARNING CAPACITY, LOSS OF CONSORTIUM, PUNITIVE DAMAGES, AND OTHER DAMAGES

Plaintiffs, by and through their counsel, bring this their Complaint for Personal Injuries, Permanent Injuries, Pain and Suffering, Medical Expenses, Lost Earnings, Diminished Earning Capacity, Loss of Consortium, Punitive Damages, and Other Damages. By operation of the Order of the Court in the matter In Re C.R. Bard, Inc. Pelvic Repair System Product Liability Litigation, MDL No. 2187, all allegations pled herein are deemed pled in any previously filed Complaint and in any Short Form Complaint hereafter filed.

PARTIES, JURISDICTION & VENUE

PLAINTIFFS

1.

Plaintiff, Talisa Taylor, had one or more of Defendant's Pelvic Mesh Products (the "Products") listed in Paragraph 11 of this Complaint inserted in her body to treat medical conditions, primarily pelvic organ prolapse (POP) and stress urinary incontinence. Plaintiff also includes Jeff Taylor, the spouse of Talisa Taylor, to file claims arising from the Products.

2.

Plaintiffs are citizens of the State of Georgia.

DEFENDANTS

3.

Defendant is C.R. Bard, Inc. ("Bard").

4.

Defendant Bard is a foreign corporation with its principal place of business in New Jersey, specifically, 730 Central Avenue, Murray Hill, New Jersey 07974.

5.

Defendant Bard may be served by serving its registered agent for service, Jean F. Holloway, 730 Central Avenue, Murray Hill, Union County, New Jersey 07974.

6.

All acts and omissions of Defendant Bard as described herein were done by its agents, servants, employees, and/or owners, acting in the course and scope of their respective agencies, services, employments, and/or ownership.

JURISDICTION AND VENUE

7.

Federal subject matter jurisdiction in this case is based upon 28 U.S.C. §1332(a), in that in each of the constituent actions there is complete diversity among Plaintiffs and Defendant and the amount in controversy exceeds $75,000.00.

8.

Defendant Bard has significant contacts with The Northern District of Georgia, such that they are subject to the personal jurisdiction of the Court in said district.

9.

Bard Urological, the division of C.R. Bard, Inc. that designed, manufactured, marketed, packaged, labeled, and sold the Product at issue in this lawsuit is located in the Northern District of Georgia in Covington, Georgia.

10.

A substantial part of the events and omissions giving rise to Plaintiffs' causes of action occurred in the Northern District of Georgia. Pursuant to 28 U.S.C. §1391(a), venue is proper in said district.

THE PELVIC MESH PRODUCTS

11.

Defendant Bard's Pelvic Mesh Products (the "Products") are as follows:

a. The Align Urethral Support System;

b. The Align TO Urethral Support System;

c. The Avaulta Anterior BioSynthetic Support System;

d. The Avaulta Posterior BioSynthetic Support System;

e. The Avaulta Plus Anterior BioSynthetic Support System;

f. The Avaulta Plus Posterior BioSynthetic Support System;

g. The Avaulta Solo Anterior Synthetic Support System;

h. The Avaulta Solo Posterior Synthetic Support System;

i. The InnerLace BioUrethral Support System;

j. The Pelvicol Acellular Collagen Matrix;

k. The PelviLace BioUrethral Support System;

l. The PelviLace TO Trans-obturator BioUrethral Support System;

m. The PelviSoft Acellular Collagen BioMesh;

n. The Pelvitex Polypropylene Mesh;

o. The Uretex SUP Pubourethral Sling;

p. The Uretex TO Trans-obturator Urethral Support System;

q. The Uretex TO2 Trans-obturator Urethral Support System;

r. The Uretex TO3 Trans-obturator Urethral Support System; and

s. The Mesh Ventralight ST 4x6 Support System.

12.

Defendant Bard designed, manufactured, packaged, labeled, marketed, sold, and distributed the subject Mesh Ventralight ST 4x6 Support System, including that specific mesh system which was implanted in Plaintiff Talisa Taylor.

FACTUAL BACKGROUND

13.

Defendant Bard's Pelvic Mesh Products contain monofilament polypropylene mesh and/or collagen.

14.

Despite claims that polypropylene is inert, the scientific evidence shows that this material as implanted in Talisa Taylor is biologically incompatible with human tissue and promotes a negative immune response in a large subset of the population implanted with Defendant's Pelvic Mesh Products.

15.

This negative response promotes inflammation of the pelvic tissue and can contribute to the formation of severe adverse reactions to the mesh.

16.

Furthermore, Defendant Bard's collagen products cause hyper-inflammatory responses leading to problems including chronic pain and fibrotic reaction.

17.

Defendant's collagen products disintegrate after implantation in the female pelvis.

18.

The collagen products cause adverse tissue reactions, and are causally related to infection, as the collagen is a foreign organic material from animals.

19.

Cross linked collagen is harsh upon the female pelvic tissue. It hardens in the body.

20.

When mesh is inserted in the female body according to the manufacturers' instructions, it creates a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities.

21.

Defendant Bard sought and obtained FDA clearance to market the Products under Section 510(k) of the Medical Device Amendment to the Food, Drug and Cosmetics Act ("The Act")

22.

Section 510(k) of the Act provides for marketing of a medical device if the device is deemed "substantially equivalent" to other predicate devices marketed prior to May 28, 1976.

23.

No formal review for safety or efficacy is required, and no formal review for safety or efficacy was ever conducted with regard to the Products.

24.

On July 13, 2011, the FDA issued a Safety Communication wherein the FDA stated that "serious complications associated with surgical mesh for transvaginal repair of POP are **not rare**" (emphasis in the original).

25.

The FDA Safety Communication also stated, "*Mesh contraction* (shrinkage) is a *previously unidentified risk* of transvaginal POP repair with mesh that has been reported in the published scientific literature and in adverse event reports to the

FDA…Reports in the literature associate mesh contraction with vaginal shortening, vaginal tightening and vaginal pain." (Emphasis in original)

26.

In a December 2011 Joint Committee Opinion, the American College of Obstetricians and Gynecologists ("ACOG") and the American Urogynecologic Society ("AUGS") also identified physical and mechanical changes to the mesh inside the body as a serious complication associated with vaginal mesh, stating:

> There are increasing reports of vaginal pain associated with changes that can occur with mesh (contraction, retraction, or shrinkage) that result in taut sections of mesh…Some of these women will require surgical intervention to correct the condition, and some of the pain appears to be intractable.

27.

The ACOG/AUGS Joint Committee Opinion also recommended, among other things, that "[p]elvic organ prolapse vaginal mesh repair should be reserved for high-risk individuals in whom the benefit of mesh placement may justify the risk."

28.

The FDA Safety Communication further indicated that the benefits of using transvaginal mesh products instead of other feasible alternatives did not outweigh the associated risks.

29.

Specifically, the FDA Safety Communication stated: "it is not clear that transvaginal POP repair with mesh is more effective than traditional non-mesh repair in all patients with POP and it may expose patients to a greater risk."

30.

Contemporaneously with the Safety Communication, the FDA released a publication titled "Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse" (the "White Paper").

31.

In the White Paper, the FDA noted that the published, peer-reviewed literature demonstrates that "[p]atients who undergo POP repair with mesh are subject to mesh-related complications that are not experienced by patients who undergo traditional surgery without mesh."

32.

The FDA summarized its findings from its review of the adverse event reports and applicable literature stating that it "has NOT seen conclusive evidence that using transvaginally placed mesh in POP repair improves clinical outcomes any more than traditional POP repair that does not use mesh, and it may expose patients to greater risk." (Emphasis in original)

33.

The FDA White Paper further stated that "these products are associated with serious adverse events…Compounding the concerns regarding adverse events are performance data that fail to demonstrate improved clinical benefit over traditional non-mesh repair."

34.

In its White Paper, the FDA advises doctors to, *inter alia*, "[r]ecognize that in most cases, POP can be treated successfully without mesh thus avoiding the risk of mesh-related complications."

35.

The FDA concludes its White Paper by stating that it "has identified serious safety and effectiveness concerns over the use of surgical mesh for the transvaginal repair of pelvic organ prolapse."

36.

Defendant Bard knew or should have known about the Products' risks and complications identified in the FDA Safety Communication and the ACOG/AUGS Joint Committee Opinion.

37.

Defendant Bard knew or should have known that the Products unreasonably exposed patients to the risk of serious harm while conferring no benefit over available feasible alternatives that do not involve the same risks.

38.

The scientific evidence shows that the material from which Defendant Bard's Products are made is biologically incompatible with human tissue and promotes a negative immune response in a large subset of the population implanted with the Products, including Plaintiff Talisa Taylor.

39.

This negative response promotes inflammation of the pelvic tissue and contributes to the formation of severe adverse reactions to the mesh, such as those experienced by Plaintiff Talisa Taylor.

40.

The FDA defines both "degradation" and "fragmentation" as "device problems" to which the FDA assigns a specific "device problem code". "Material Fragmentation" is defined as an "[i]ssue associated with small pieces of the device breaking off unexpectedly" and "degraded" as an "[i]ssue associated with a deleterious change in the chemical structure, physical properties, or appearance in the materials that are used in device construction".

41.

The Products were unreasonably susceptible to degradation and fragmentation inside the body.

42.

The Products were unreasonably susceptible to shrinkage and contraction inside the body.

43.

The Products were unreasonably susceptible to "creep" or the gradual elongation and deformation when subject to prolonged tension inside the body.

44.

The Products have been and continue to be marketed to the medical community and to patients as safe, effective, reliable, medical devices, implanted by safe and effective, minimally invasive surgical techniques, and as safer and more effective as compared to available feasible alternative treatments of pelvic organ prolapse and stress urinary incontinence, and other competing products.

45.

Defendant Bard omitted the risks, dangers, defects, and disadvantages of the Products, and advertised, promoted, marketed, sold, and distributed the Products as safe medical devices when Defendant Bard knew or should have known that the Products were not safe for their intended purposes, and that the Products would

cause, and did cause, serious medical problems, and in some patients, including Plaintiff Talisa Taylor, catastrophic injuries.

46.

Contrary to Defendant Bard's representations and marketing to the medical community and to the patients themselves, the Products have high rates of failure, injury, and complications, the Products fail to perform as intended, require frequent and often debilitating re-operations, and have caused severe and irreversible injuries, conditions, and damage to a significant number of women, including the Plaintiff Talisa Taylor, making them defective under the law.

47.

The specific nature of the Products' defects includes, but is not limited to, the following:

a. The use of polypropylene and collagen material in the Products and the immune reactions that result from such material, causing adverse reactions and injuries;

b. The design of the Products to be inserted into and through an area of the body with high levels of bacteria that can adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c. Biomechanical issues with the design of the Products, including, but not limited to, the propensity of the Products to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

d. The use and design of arms and anchors in the Products, which, when placed in women, are likely to pass through contaminated spaces and that can injure major nerve routes in the pelvic region;

e. The propensity of the Products to "creep", or to gradually elongate and deform when subject to prolonged tension inside the body;

f. The inelasticity of the Products, causing them to be improperly mated to the delicate and sensitive areas of the vagina and pelvis where they are implanted, and causing pain upon normal daily activities that involve movement in the pelvic region (e.g., intercourse, defecation, walking);

g. The propensity of the Products for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;

h. The hyper-inflammatory responses to collagen leading to problems including chronic pain and fibrotic reaction;

i. The propensity of the collagen products to disintegrate after implantation in the female pelvis, causing pain and other adverse reactions;

j. The adverse tissue reactions caused by the collagen products, which are causally related to infection, as the collagen is a foreign organic material from animals;

k. The harshness of cross linked collagen upon the female pelvic tissue, and the hardening of the product in the body; and

l. The creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanting according to the manufacturers' instructions.

48.

The Products are also defective due to Defendant's failure to adequately warn or instruct Plaintiff Talisa Taylor and/or her health care providers of subjects including, but not limited to, the following:

a. The Products' propensities to contract, retract, and/or shrink inside the body;

b. The Products' propensities for degradation, fragmentation, and/or creep;

c. The Products' inelasticity preventing proper mating with the pelvic floor and vaginal region;

d. The rate and manner of mesh erosion or extrusion;

e. The risk of chronic inflammation resulting from the Products;

f. The risk of chronic infections resulting from the Products;

g. The risk of permanent vaginal or pelvic scarring as a result of the Products;

h. The risk of recurrent, intractable pelvic pain and other pain resulting from the Products;

i. The need for corrective or revision surgery to adjust or remove the Products;

j. The severity of complications that could arise as a result of implantation of the Products;

k. The hazards associated with the Products;

l. The Products' defects described herein;

m. Treatment of pelvic organ prolapse and stress urinary incontinence with the Products is no more effective than feasible available alternatives;

n. Treatment of pelvic organ prolapse and stress urinary incontinence with the Products exposes patients to a greater risk than feasible available alternatives;

o. Treatment of pelvic organ prolapse and stress urinary incontinence with the Products makes future surgical repair more difficult than feasible available alternatives;

p. Use of the Products puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

q. Removal of the Products due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

r. Complete removal of the Products may not be possible and may not result in complete resolution of the complications, including pain.

49.

Defendant Bard has underreported information about the propensity of the Products to fail and cause injury and complications, and have made unfounded representations regarding the efficacy and safety of the Products through various means and media.

50.

Defendant Bard failed to perform proper and adequate testing and research in order to determine and evaluate the risks and benefits of the Products.

51.

Defendant Bard failed to design and establish a safe, effective procedure for removal of the Products, or to determine if a safe, effective procedure for removal of the Products exists.

52.

Feasible and suitable alternatives to the Products have existed at all times relevant that do not present the same frequency or severity of risks as do the Products.

53.

The Products were at all times utilized and implanted in a manner foreseeable to Defendant Bard, as Defendant Bard generated the instructions for use, created the procedures for implanting the devices, and trained the implanting physician.

54.

Defendant Bard provided incomplete and insufficient training and information to physicians regarding the use of the Products and the aftercare of patients implanted with the Products.

55.

The Product or products implanted in Plaintiff Talisa Taylor were in the same or substantially similar condition as they were when they left Defendant Bard's possession, and in the condition directed by and expected by Defendant Bard.

56.

The injuries, conditions, and complications suffered by numerous women around the world who have been implanted with the Products include, but are not limited to, erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia (pain during sexual intercourse), blood loss,

neuropathic and other acute and chronic nerve damage and pain, pudendal nerve damage, pelvic floor damage, and chronic pelvic pain.

57.

In many cases, including Plaintiff Talisa Taylor, the women have been forced to undergo extensive medical treatment, including, but not limited to, operations to locate and remove mesh, operations to attempt to repair pelvic organs, tissue, and nerve damage, the use of pain control and other medications, injections into various areas of the pelvis, spine, and the vagina, and operations to remove portions of the female genitalia.

58.

The medical and scientific literature studying the effects of Defendant's mesh products, like that of the product(s) implanted in Plaintiff Talisa Taylor, has examined each of these injuries, conditions, and complications, and has reported that they are causally related to the Products.

59.

Removal of contracted, eroded, and/or infected mesh can require multiple surgical interventions for removal of mesh and results in scarring on fragile compromised pelvic tissue and muscles.

60.

At all relevant times herein, Defendant Bard continued to promote the Products as safe and effective even when no clinical trials had been done supporting long or short term efficacy.

61.

In doing so, Defendant Bard failed to disclose the known risks and failed to warn of known or scientifically knowable dangers and risks associated with the Products.

62.

At all relevant times herein, Defendant Bard failed to provide sufficient warnings and instructions that would have put Plaintiff Talisa Taylor and the general public on notice of the dangers and adverse effects caused by implantation of the Products.

63.

The Products are designed, manufactured, distributed, sold, and/or supplied by Defendant Bard were defective as marketed due to inadequate warnings, instructions, labeling, and/or inadequate testing in the presence of Defendant's knowledge of lack of safety.

64.

As a result of having the Products implanted in her, Plaintiff Talisa Taylor has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

65.

On or about June 7, 2012, Plaintiff Talisa Taylor was implanted with the Mesh Ventralight ST 4x6 Support System ("Product") manufactured by Bard during surgery performed by Dr. Lynwood Cleaveland at Rockdale Medical Center in Conyers, Georgia.

66.

The Product was implanted in Plaintiff Talisa Taylor to treat her pelvic organ prolapse, and ventral hernia with bladder involvement, the use for which the Product was designed, marketed, and sold.

67.

As a result of having the Product implanted in her, Plaintiff Talisa Taylor has experienced significant mental and physical pain and suffering, she has sustained permanent injury and permanent and substantial physical deformity, she

has undergone or will undergo corrective surgery or surgeries, and she has endured impaired physical relations with her husband, Plaintiff Jeff Taylor.

68.

Defendant Bard designed, manufactured, marketed, packaged, labeled, and sold the Mesh Ventralight ST 4x6 Support System, including the product that was implanted in Plaintiff Talisa Taylor.

CAUSES OF ACTION

COUNT I: NEGLIGENCE

69.

Paragraphs 1-68 of this Complaint are hereby incorporated by reference as if fully set forth herein.

70.

Defendant Bard had a duty to individuals, including Plaintiff Talisa Taylor, to use reasonable care in designing, manufacturing, marketing, labeling, packaging, and selling the Products.

71.

Defendant Bard was negligent in failing to use reasonable care as described in designing, manufacturing, marketing, labeling, packaging, and selling the Products. Defendant Bard breached their aforementioned duty by:

a. Failing to design the Products so as to avoid an unreasonable risk of harm to women in whom the Products were implanted, including Plaintiff Talisa Taylor;

b. Failing to manufacture the Products so as to avoid an unreasonable risk of harm to women in whom the Products were implanted, including Plaintiff Talisa Taylor;

c. Failing to use reasonable care in the testing of the Products so as to avoid an unreasonable risk of harm to women in whom the Products were implanted, including Plaintiff Talisa Taylor;

d. Failing to use reasonable care in inspecting the Products so as to avoid an unreasonable risk of harm to women in whom the Products were implanted, including Plaintiff Talisa Taylor; and

e. Otherwise negligently or carelessly designing, manufacturing, marketing, labeling, packaging, and/or selling the Products.

72.

The reasons that Defendant Bard's negligence cause the Products to be unreasonably dangerous and defective include, but are not limited to:

a. The use of polypropylene material and/or collagen material in the Products and the immune reaction that results from such material, causing adverse reactions and injuries;

b. The design of the Products to be inserted into and through an area of the body with high levels of bacteria that adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c. Biomechanical issues with the design of the Products, including, but not limited to, the propensity of the Products to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

d. The use and design of arms and anchors in the Products, which, when placed in the women, are likely to pass through contaminated spaces and injure major nerve routes in the pelvic region;

e. The propensity of the Products for "creep", or to gradually elongate and deform when subject to prolonged tension inside the body;

f. The inelasticity of the Products, causing them to be improperly mated to the delicate and sensitive areas of the pelvis where they are implanted, and causing pain upon normal daily activities that involve movement in the pelvis (e.g., intercourse, defecation);

g. The propensity of the Products for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;

h. The hyper-inflammatory responses to collagen leading to problems including chronic pain and fibrotic reaction;

i. The propensity of the collagen products to disintegrate after implantation in the female pelvis, causing pain and other adverse reactions;

j. The adverse tissue reactions caused by the collagen products, which are causally related to infection, as the collagen is a foreign organic material from animals;

k. The harshness of cross linked collagen upon the female pelvic tissue, and the hardening of the product in the body; and

l. The creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanting according to the manufacturers' instructions.

73.

Defendant Bard also negligently failed to warn or instruct Plaintiff Talisa Taylor and/or her health care providers of subjects including, but not limited to, the following:

a. The Products' propensities to contract, retract, and/or shrink inside the body;

b. The Products' propensities for degradation, fragmentation, and/or creep;

c. The Products' inelasticity preventing proper mating with the pelvic floor and vaginal region;

d. The rate and manner of mesh erosion or extrusion;

e. The risk of chronic inflammation resulting from the Products;

f. The risk of chronic infections resulting from the Products;

g. The risk of permanent vaginal or pelvic scarring as a result of the Products;

h. The risk of recurrent, intractable, pelvic pain and other pain resulting from the Products;

i. The need for corrective surgery to adjust or remove the Products;

j. The severity of complications that could arise as a result of implantation of the Products;

k. The hazards associated with the Products;

l. The Products' defects described herein;

m. Treatment of pelvic organ prolapse and stress urinary incontinence with the Products is no more effective than feasible available alternatives;

n. Treatment of pelvic organ prolapse and stress urinary incontinence with the Products exposes patients to greater risk than feasible available alternatives;

o. Treatment of pelvic organ prolapse and stress urinary incontinence with the Products makes future surgical repair more difficult than feasible available alternatives;

p. Use of the products puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

q. Removal of the Products due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

r. Complete removal of the Products may not be possible and may not result in complete resolution of the complications, including pain.

74.

As a direct and proximate result of Defendant Bard's negligence, Plaintiff Talisa Taylor has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

COUNT II: STRICT LIABILITY – DESIGN DEFECT

75.

Plaintiffs incorporate by reference paragraphs 1-74 of this Complaint as if fully set forth herein.

76.

The Products implanted in Plaintiff Talisa Taylor were not reasonably safe for their intended uses and were defective as described herein with respect to their design. As previously stated, the Products' design defects include, but are not limited to:

a. The use of polypropylene material and/or collagen material in the Products and the immune reaction that results from such material, causing adverse reactions and injuries;

b. The design of the Products to be inserted into and through an area of the body with high levels of bacteria that adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c. Biomechanical issues with the design of the Products, including, but not limited to, the propensity of the Products to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

d. The use and design of arms and anchors in the Products, which, when placed in the women, are likely to pass through contaminated spaces and injure major nerve routes in the pelvic region;

e. The propensity of the Products for "creep', or to gradually elongate and deform when subject to prolonged tension inside the body;

f. The inelasticity of the Products, causing them to be improperly mated to the delicate and sensitive areas of the pelvis where they are implanted, and causing pain upon normal daily activities that involve movement in the pelvis (e.g., intercourse, defecation);

g. The propensity of the Products for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;

h. The hyper-inflammatory responses to collagen leading to problems including chronic pain and fibrotic reaction;

i. The propensity of the collagen products to disintegrate after implantation in the female pelvis, causing pain and other adverse reactions;

j. The adverse tissue reactions caused by the collagen products, which are causally related to infection, as the collagen is a foreign organic material from animals;

k. The harshness of cross linked collagen upon the female pelvic tissue, and the hardening of the product in the body; and

l. The creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanting according to the manufacturers' instructions.

77.

As a direct and proximate result of the Products' aforementioned defects as described herein, Plaintiff Talisa Taylor has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo future medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

78.

Defendant Bard is strictly liable to Plaintiff Talisa Taylor for designing, manufacturing, marketing, labeling, packaging, and selling a defective product(s).

COUNT III: STRICT LIABILITY – MANUFACTURING DEFECT

79.

Plaintiffs incorporate by reference paragraphs 1-78 of this Complaint as if fully set forth herein.

80.

The Product(s) implanted in Plaintiff Talisa Taylor were not reasonably safe for their intended uses and were defective as described herein as a matter of law

with respect to their manufacture, in that they deviated materially from Defendant's design and manufacturing specifications in such a manner as to pose unreasonable risks of serious bodily harm to Plaintiff Talisa Taylor.

81.

As a direct and proximate result of the Products' aforementioned defects as described herein, Plaintiff Talisa Taylor has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and/or corrective surgery and hospitalization, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

82.

Defendant Bard is strictly liable to Plaintiff Talisa Taylor for designing, manufacturing, marketing, labeling, packaging, and selling a defective product(s).

COUNT IV: STRICT LIABILITY – FAILURE TO WARN

83.

Plaintiffs incorporate by reference paragraphs 1-82 of this Complaint as if fully set forth herein.

84.

The Product(s) implanted in Plaintiff Talisa Taylor were not reasonably safe for their intended uses and were defective as described herein as a matter of law

due to their lack of appropriate and necessary warnings. Specifically, Defendant Bard did not provide sufficient or adequate warnings regarding, among other subjects:

a. The Products' propensities to contract, retract, and/or shrink inside the body;

b. The Products' propensities for degradation, fragmentation, disintegration, and/or creep;

c. The Products' inelasticity preventing proper mating with the pelvic floor and vaginal region;

d. The rate and manner of mesh erosion or extrusion;

e. The risk of chronic inflammation resulting from the Products;

f. The risk of chronic infections resulting from the Products;

g. The risk of permanent vaginal or pelvic scarring as a result of the Products;

h. The risk of recurrent, intractable pelvic pain and other pain resulting from the Products;

i. The need for corrective or revision surgery to adjust or remove the Products;

j. The severity of complications that could arise as a result of implantation of the Products;

k. The hazards associated with the Products;

l. The Products' defects described herein;

m. Treatment of pelvic organ prolapse and stress urinary incontinence with the Products is no more effective than feasible available alternatives;

n. Treatment of pelvic organ prolapse and stress urinary incontinence with the Products exposes patients to a greater risk than feasible available alternatives;

o. Treatment of pelvic organ prolapse and stress urinary incontinence with the Products makes future surgical repair more difficult than feasible available alternatives;

p. Use of the Products puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

q. Removal of the Products due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

r. Complete removal of the Products may not be possible and may not result in complete resolution of the complications, including pain.

85.

As a direct and proximate result of the Products' aforementioned defects as described herein, Plaintiff Talisa Taylor has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone

medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

86.

Defendant Bard is strictly liable to Plaintiff Talisa Taylor for designing, manufacturing, marketing, labeling, packaging, and selling a defective product(s).

COUNT V: BREACH OF EXPRESS WARRANTY

87.

Plaintiffs incorporate by reference paragraphs 1-86 of this Complaint as if fully set forth herein.

88.

Defendant Bard made assurances as described herein to the general public, hospitals, and health care professionals that the Products were safe and reasonably fit for their intended purposes.

89.

Plaintiff Talisa Taylor and/or her healthcare provider chose the Products based upon Defendant's warranties and representations as described herein regarding the safety and fitness of the Products.

90.

Plaintiff Talisa Taylor, individually and/or by and through her physician, reasonably relied upon Defendant's express warranties and guarantees that the Products were safe, merchantable, and reasonably fit for their intended purposes.

91.

Defendant Bard breached these express warranties because the Product(s) implanted in Plaintiff Talisa Taylor were unreasonably dangerous and defective as described herein and not as Defendant had represented.

92.

Defendant Bard's breach of their express warranties resulted in the implantation of an unreasonably dangerous and defective product(s) in the body of Plaintiff Talisa Taylor, placing said Plaintiff's health and safety in jeopardy.

93.

As a direct and proximate result of Defendant Bard's breach of the aforementioned express warranties, Plaintiff Talisa Taylor has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

COUNT VI: BREACH OF IMPLIED WARRANTY

94.

Plaintiffs incorporate by reference paragraphs 1-93 of this Complaint as if fully set forth herein.

95.

Defendant Bard impliedly warranted that the Products were merchantable and were fit for the ordinary purposes for which they were intended.

96.

When the Products were implanted in Plaintiff Talisa Taylor to treat her pelvic organ prolapse and/or stress urinary incontinence, the Products were being used for the ordinary purposes for which they were intended.

97.

Plaintiff Talisa Taylor, individually and/or by and through her physician, relied upon Defendant's implied warranties of merchantability in consenting to have the Products implanted in her.

98.

Defendant Bard breached these implied warranties of merchantability because the Product(s) implanted in Plaintiff Talisa Taylor were neither merchantable nor suited for their intended uses as warranted.

99.

Defendant Bard's breach of their implied warranties resulted in the implantation of unreasonably dangerous and defective products in the body of Plaintiff Talisa Taylor, placing said Plaintiff's health and safety in jeopardy.

100.

As a direct and proximate result of Defendant Bard's breach of the aforementioned implied warranties, Plaintiff Talisa Taylor has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

COUNT VII: LOSS OF CONSORTIUM

101.

Plaintiffs incorporate by reference paragraphs 1-100 of this Complaint as if fully set forth herein.

102.

As a direct and proximate result of the above-described injuries sustained by Plaintiff Talisa Taylor, her husband, Jeff Taylor, has suffered a loss of his wife's consortium, companionship, society, affection, services, and support.

COUNT VIII: PUNITIVE DAMAGES

103.

Plaintiffs incorporate by reference paragraphs 1-102 of this Complaint as if fully set forth herein.

104.

Defendant Bard sold their Products to the healthcare providers of Plaintiff Talisa Taylor and other healthcare providers in the state of implantation and throughout the United States without doing adequate testing to ensure that the Products were reasonably safe for implantation in the female pelvic area.

105.

Defendant Bard sold the Products to Plaintiff Talisa Taylor's healthcare providers and other healthcare providers in the state of implantation and throughout the United States in spite of their knowledge that the Products can shrink, disintegrate, and/or degrade inside the body, and cause the other problems heretofore set forth in this Complaint, thereby causing severe and debilitating injuries suffered by Plaintiff Talisa Taylor and numerous other women.

106.

Defendant Bard ignored reports from patients and healthcare providers throughout the United States and elsewhere of the Products' failures to perform as intended, which lead to the severe and debilitating injuries suffered by Plaintiff

Talisa Taylor and numerous other women. Rather than doing adequate testing to determine the cause of these injuries, or to rule out the Products' designs or the processes by which the Products are manufactured as the cause of these injuries, Defendant Bard chose instead to continue to market and sell the Products as safe and effective.

107.

Defendant Bard knew the Products were unreasonably dangerous in light of their risks of failure, pain and suffering, loss of life's enjoyment, remedial surgeries and treatments in an effort to cure the conditions proximately related to the use of the Products, as well as other severe and personal injuries which were permanent and lasting in nature.

108.

Defendant Bard withheld material information from the medical community and the public in general, including Plaintiff Talisa Taylor, regarding the safety and efficacy of the Products.

109.

Defendant Bard knew and recklessly disregarded the fact that the Products caused debilitating and potentially life altering complications with greater frequency than feasible alternative methods and/or products used to treat pelvic organ prolapse and stress urinary incontinence.

110.

Defendant Bard misstated and misrepresented data and continue to misrepresent data so as to minimize the perceived risk of injuries caused by the Products.

111.

Notwithstanding the foregoing, Defendant Bard continues to aggressively market the Products to consumers, without disclosing the true risks associated with the Products.

112.

Defendant Bard knew of the Products' defective and unreasonably dangerous nature, but continued to manufacture, market, distribute, and sell the Products so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff Talisa Taylor.

113.

Defendant Bard continues to conceal and/or fail to disclose to the public, including Plaintiff Talisa Taylor, the serious complications associated with the use of the Products to ensure continued and increased sales of the Products.

114.

Defendant Bard's conduct as described herein shows willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care which raises the

presumption of conscious indifference to consequences, thereby justifying an award of punitive damages.

WHEREFORE, Plaintiffs Talisa Taylor and Jeff Taylor demand a trial by jury, judgment against Defendant for compensatory and punitive damages in an amount exceeding Seventy-Five Thousand Dollars ($75,000.00) as well as costs, attorney fees, interest, or any other relief, monetary or equitable, to which they are entitled.

PLAINTIFFS DEMAND A TRIAL BY JURY.

KAPLAN & SEIFTER

/s/ Brad C. Kaplan

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/s/ James I. Seifter

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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

TALISA TAYLOR AND JEFF TAYLOR, Plaintiff, vs. C.R. BARD, INC., Defendant.	CIVIL ACTION FILE No.: _____ JURY TRIAL DEMANDED

CERTIFICATE OF COMPLIANCE

This is to certify that the foregoing pleading complies with the font and point selections approved by the Court in Local Rules 5.1. It is prepared in Times New Roman 14 Point Font.